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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,826

12/03/2003

Andrew Thomas Forsberg

47563.0017

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08/06/2008

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,826	Applicant(s) FORSBERG ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39,41-49,51-73,76 and 77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39,41-49,51-73,76 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 May 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 35, 37, 38, 41-48, 55 and 57-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), filament (34), anchor (32), and sealing plug (30) wherein the anchor is seated in a multilevel nest or recess (see figure 1). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The tissue

puncture is in a blood vessel (see figure 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 36, 39, 49, 51-54, 56, 63-66, 71-73, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) in view of Bonutti (5,814,073).** Nash reference does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an introducer sheath with resilient tips as taught by Bonutti reference with the closure device of Nash reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

6. Furthermore, Nash reference states the closure device may be used with any typical introducer sheath (see column 4, lines 24-29). The tip of the insertion sheath

would slide into a gap between the anchor and the nest because the tip of the sheath is resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of Nash reference when that point is reached.

7. **Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (5,282,827) in view of Bonutti (5,814,073).** Kensey reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32', see figures 34 and 35), and a sealing plug (30). The anchor is indented because of the area between the raised cap portions (32b) and the proximal end of the anchor. The indent will cause a gap between the anchor and the carrier tube. The tissue puncture is in a blood vessel (see figures 16-18). The device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3). The anchor is moved away from and oriented transverse to the carrier tube (see figure 22). However, Kensey reference does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an introducer sheath with resilient tips as taught by Bonutti

reference with the closure device of Kensey reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

Response to Arguments

Applicant's arguments filed 21 May 2008 have been fully considered but they are not persuasive.

Regarding claims 35, 37, 44, and 45, Examiner notes that it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Since applicant merely claims providing the device with the multi-level nest, and doesn't claim how that structure is used in a method in a manipulative sense, the arguments that the prior art does not disclose the multi-level nest as claimed are not persuasive because the prior art references do perform the method steps substantially as claimed.

Regarding claims 49, the gap between the anchor and tube of Nash is defined in directions both transverse to and axially along the length of the tube, thereby meeting the claim limitation requiring the "gap between the anchor and carrier tube in a direction that is transverse to the carrier tube."

Regarding claims 63 and 71, the outer surface of the carrier tube of Nash has a recess (see figure 1), and the sheath of the combination of Nash and Bonutti has the sheath tips passing into the gap underneath the anchor before the anchor is deployed.

Regarding claim 67, the indentation that forms a gap in the anchor of Kensey is defined between the raised portions (32B) and the extreme proximal end of the anchor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731